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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/171,432

11/23/1998

HOWARD A. FIELDS

03063-0231US

8029

23859

7590

11/21/2001

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ATLANTA, GA 30303-1811

EXAMINER

BRUMBACK, BRENDA G

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 11/21/2001

*Me*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/171,432

Applicant(s)

FIELDS ET AL.

Examiner

Brenda G. Brumback

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 70-76 is/are pending in the application.
- 4a) Of the above claim(s) 74-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. This action is responsive to the amendment filed 08/20/2001. Claims 70-72 were amended. Claims 73-76 have been withdrawn from consideration as directed to a nonelected invention. Claims 70-72 are under examination.

#### ***Election/Restriction***

2. This application contains claims 73-76 drawn to an invention nonelected in Paper No. 11, 16, and 20. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Priority***

3. Applicant's submission of the new declaration identifying Provisional Application No. 60/015,644 by application number and filing date is acknowledged.

#### ***Specification***

4. The abstract filed 08/20/2001 is objected to as not having been submitted on a separate sheet. A new abstract on a **separate sheet** is required.

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***Claim Rejections - 35 USC § 112***

5. The rejection of claims 70-72 are rejected under 35 U.S.C. 112, second paragraph, is maintained.

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Applicant's amendments to add the full name of the hepatitis A virus at the first occurrence in the claims and to delete the term "about" from the claims are acknowledged; however, the claims remain rejected under 35 U.S.C. 112, second paragraph, for the remaining reasons of record. Applicant's arguments have been fully considered but they are not persuasive for the following reasons.

Regarding the rejection for "substantially similar to a portion", applicant points to the specification at page 4, line 42, through page 5, line 26 as disclosing the meaning of the phrase. Applicant argues that this portion of the specification discloses that the peptides are defined as being capable of binding to an antibody specifically immunoreactive with a peptide selected from a defined group of peptides. The referenced portion of the disclosure, however, does not set forth the metes and bounds of the encompassed peptides other than to disclose that the peptides bind to an antibody which is immunoreactive with one of the peptides listed in the disclosure. It does not set forth the structural metes and bounds of such peptides, but merely defines a single property of the peptides, *i.e.*, binding to any antibody which binds to any portion of any of the recited list of peptides. The specification fails to delineate what specific peptides are encompassed. Thus, the metes and bounds of the claimed invention cannot be determined and the claims are indefinite.

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Applicant argues that “portion” indicates any fraction up to and including the complete item and that it would be clear to anyone of skill in the art that a portion of the P2A protein means a fraction or fragment of the P2A protein. While applicant’s argument is noted, the specification fails to teach the metes and bounds of such a “portion”. According to applicant’s comments in the response, such a portion can encompass any fraction of the protein. Is such a fraction intended to encompass as little as a single amino acid? ...more than a single amino acid? ...how many more amino acids? It remains unclear what the claimed portions, fragments, or fractions encompass.

Regarding “conservative variations”, applicant points to the disclosure at page 13, lines 14-19 as used in the specification to describe nucleic acids and points to the “conservative substitution tables” at page 13 as defining “conservative variations”. The referenced portion of the disclosure, however, teaches conservative variations as describing nucleic acids, not amino acid sequences, as is claimed in the present claims. It would appear from the disclosure that “conservative variations” is intended to describe nucleic acids which encode the same amino acid sequences, not conservative substitutions for amino acids. Thus, it remains unclear whether the term “variations” is intended to have the same meaning as “substitutions” or whether the meaning is different and the claims remains indefinite.

Regarding the numbering system, applicant argues that the nomenclature for the HAV polyprotein is well-established; however, applicant has not pointed out any reference sequence upon which this numbering system is based. The portion of the disclosure referenced in Tables

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2-11 fails to provide such a reference sequence. Absent such a reference sequence, the metes and bounds of the claimed invention cannot be ascertained and the claims are indefinite.

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***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 70-72 under 35 U.S.C. 103(a) as being unpatentable over Chiron Corporation is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant's argument that Chiron neither made nor tested any peptide corresponding to AA 792-848 of HAV in conjunction with the cited application. Firstly, applicant's claims are directed to any HAV peptide which comprises an amino acid sequence which is substantially similar to a portion of AA 792-980 of the HAV P2A protein. Applicant's claims do not require that the peptide correspond to AA 792-848 of HAV, but rather merely require that the peptide be substantially similar. According to applicant's disclosure, any peptide which is immunoreactive with any antibody that is immunoreactive with any of the claimed peptides encompassed within AA 792-848 of the HAV polyprotein is considered to be substantially similar. The peptide disclosed by Chiron is such a peptide. Secondly, applicant's argument that at the time of the invention it was well-established that the nonstructural proteins of HAV, including the P2A protein, were not immunogenic does not appear to be relevant to the claims as presently

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amended, because they are drawn to antigenically reactive peptides, not to immunogenic peptides. Applicant's statement regarding attached Exhibits A-D with the Khudyakov et al. reference is noted; however no such exhibits were found with the response. Applicant's argument that Khudyakov et al. establishes that the P2A nonstructural proteins were not taught in the art to be immunogenic is not understood, as applicant has not pointed out where in the reference such a teaching is found. Rather, in the last sentence of the abstract in the Khudyakov et al. reference, Khudyakov teaches "collectively these data demonstrate that HAV structural and nonstructural proteins contain antigenic epitopes that can be efficiently modeled with short synthetic peptides". Applicant alleges that there would have been no expectation of success in producing peptides based on the Khudyakov et al. article, but the Khudyakov et al. article would seem to teach toward a reasonable expectation of success in producing the antigenically reactive peptides of the claimed invention.

7. Applicant's amendment of claim 70 to correct a clerical error is acknowledged.

***Conclusion***


8. No claims are allowed.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

*bbs*  
Brenda Brumback  
November 10, 2001

  
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